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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,620	01/13/2006	Pninna Fishman	FISHMAN18A	1534

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BROWDY AND NEIMARK, P.L.L.C.
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SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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01/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,620

Applicant(s)

FISHMAN ET AL.

Examiner

Michael C. Henry

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) 7 and 8 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/13/06 & 04/20/07</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-10 are pending in application

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishman (WO2004/045627 A1).

In claim 1, applicant claims a method for the treatment of accelerated bone resorption in a mammal subject, the method comprises administering to said subject in need of said treatment an amount of an A3 adenosine receptor agonist (A3AR agonist), the amount being effective to inhibit bone resorption.

Fishman discloses a method of treating inflammatory arthritis comprising administering to a subject an A3 adenosine receptor agonist (A3AR agonist) (see abstract and claims). Furthermore, Fishman discloses uses the A3 receptor agonists IB-MECA and CI-IB-MECA for the said treatment (see abstract and claims). Also, Fishman reduces the bone loss (bone

resorption) in a subject by administering to the subject IB-MECA. In addition, Fishman measures the loss of bone and reports that bone loss was markedly lower in the subjects treated with IB-MECA(see histology score in example 1C). Claims 2-6 are drawn said method, wherein the subject is human, the treatment of bone resorption is induced by specific conditions, the administration is oral, the A3AR agonist is administered specific times per day and the use of specific A3AR agonist including IB-MECA and CL-IB-MECA.

The difference between applicant's claimed method and the method of Fishman is that Fishman's do not disclose that the bone resorption that is treated is accelerated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Fishman, to treat bone resorption (bone loss) in a subject regardless of the type of bone loss by administering to the said subject the A3AR agonist such as IB-MECA or CL-IB-MECA, since Fishman discloses that A3AR agonist such as IB-MECA or CL-IB-MECA can be used to treat bone resorption (bone loss).

One having ordinary skill in the art would have been motivated in view of Fishman, to treat bone resorption (bone loss) in a subject, regardless of the type of bone loss, by administering to the said subject an A3AR agonist such as IB-MECA or CL-IB-MECA, because a skilled artisan would reasonably be expected to use or administer A3AR agonist such as IB-MECA or CL-IB-MECA, to treat bone resorption (the same condition or disease) based on factors such as type and/or severity of the condition or disorder. It should be noted that the use of different schedules of administration or dosages are common in the art and is well within the

purview of a skilled artisan and depends on factors such as the severity or type of the rheumatoid arthritis and the weight, age and type of the subject treated.

Allowable Subject Matter

Claims 7 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The method recited in claims 7 and 8 treats accelerated bone resorption with compounds that possess structural differences to the compounds of the prior art and these differences are not suggested in the prior art, nor are obvious over the prior art. For example, the compounds of the claims 7 and 8 contain chemical moieties or substituents on N6 of the purine ring that are different, not suggested in the prior art, nor are obvious over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

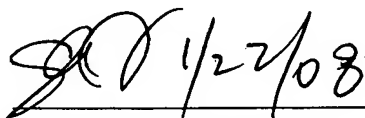
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry



Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

January 21, 2008.